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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,102	11/25/2003	Peter M. Bonutti	780-A03-012C	6375
33771 7590 12/17/2007 PAUL D. BIANCO: FLEIT, KAIN, GIBBONS, GUTMAN, BONGINI, & BIANCO P.L. 21355 EAST DIXIE HIGHWAY SUITE 115 MIAMI, FL 33180			EXAMINER PHILOGENE, PEDRO	
			ART UNIT 3733	PAPER NUMBER
			MAIL DATE 12/17/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

#

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/722,102	BONUTTI, PETER M.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Pedro Philogene	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-20 and 22-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-20 and 22-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/9/07</u>                                                   | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-20, 22-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsen, III et al. (4,979,949).

With respect to claim 13, Matsen, III et al disclose a total knee replacement comprising a disposable cutting guide (215, 238) fabricated from a polymeric material and designed for a single use, as set forth in column 25, lines 9-13 having a body for forming a cut on a bone in preparation to receive a total knee joint replacement component, having a body dimensioned for attachment to a surface of an end portion of the bone (12) free of an extramedullary or intramedullary alignment rod; as best seen in FIGS. 4, 15, 19, and at least one guide surface (238) dimensioned for engagement with a cutting tool (222) to thereby direct the cutting tool wherein the cutting guide, being both polymeric and disposable, is readily modified in successive iterations for new or customized instrumentation.

With respect to claims 14-18,39 Matsen, III et al discloses all the limitations, as best seen in FIGS.1-27, and as set forth in column 21, lines 25-30, column 22, lines 7-68, column 23, lines 1-68, column 24, lines 1-68, column 25, lines 1-39, column 227, lines 5-10, line 68, column 29, lines 1-14.

With respect to claims 1, 2, 4-12, 19, 20, 22-38, the method steps, as set forth, would have been inherently carried out in the operation of the device, as set forth above. As to the step of expanding the incision from an unexpanded configuration to an expanded configuration by applying force against opposite edge portions of the incision, this step is inherent.

### ***Response to Amendment***

Applicant's arguments, see Remarks, filed 10/9/07, with respect to the rejection(s) of claim(s) 1-37 under 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Matsen, III et al. Matsen, III et al disclose a disposable cutting guide fabricated from polymeric material and designed for a single use and is readily modified in successive iterations for new customized instrumentation (at least in part). Furthermore the passage "is readily modified in successive iterations for new or customized instrumentations" is considered as functional limitations, therefore not given any patentable weight. Because first applicant claims that the cutting guide is disposable and should be a single use device, then applicant claims that the device "is readily modified in successive iterations".

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Pedro Philogene  
December 12, 2007



PEDRO PHILOGENE  
ATTORNEY AT LAW